

### **REMARKS**

After the foregoing amendment, claims 1-18, 21 and 24-38 are active in the present application. Claim 1 has been amended to more particularly point out and distinctly claim the invention. Claims 6, 7 and 21 have been amended to be consistent with claim 1. No new matter has been added to the application as a result of the amendment to claim 1 or claims 6, 7 and 21. A Request for Continued Examination (RCE) is being filed with this response.

#### **Interview**

The Applicants would like to express their sincere appreciation to the Examiner for the courtesies extended during the telephone interview conducted on April 19, 2004. During the interview, the applicants' undersigned attorney discussed the proposed changes to claim 1 as they related to the present invention and the currently pending rejection of claim 1. Both the Lauks et al. and Ozawa et al. references were discussed and distinctions within the language of claim 1 were pointed out to the Examiner. The Examiner suggested that additional distinctions be added to claim 1 to clarify the fact that the indicia on the applicants' test cell is "unique" in the sense that no two test cells will have the same indicia regardless of the test being performed. It was further agreed that claim 1 would be amended to clarify the fact that one of the purposes of having the unique indicia on the test cell is to preclude a test cell from being used more than once. Applicants believe that the foregoing amendment to claim 1 addresses the issue discussed during the telephone interview.

#### **Art Rejections**

Claims 1-12, 17, 18, 21, 24, 26-28, 30 and 35-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,096,669 (Lauks et al.) in view of U.S. Patent No. 5,690,593 (Ozawa et al.). It is the position of the Examiner that Lauks et al. discloses all of the limitations set forth in the cited claims but does not explicitly set forth a reader for the indicia or a bar code. It is the Examiner's position that Ozawa et al. teaches, in an alternate electric chemical system, that other indicia for identifying details about a particular test cell being manipulated may be employed. The Ozawa et al. patent suggests bar codes and a programmable

memory may be used for such information. The Examiner therefore concludes that it would have been obvious to one of ordinary skill in the art to utilize the teachings of Ozawa et al. for the system of Lauks et al. in order to further improve the measurement accuracy of individual sensors. And for the reasons as set forth below, the applicants respectfully traverse this rejection.

The present invention comprises a system for conducting a plurality of different medical diagnostic tests. The system includes a hand held portable self contained instrument and a series of disposable, single use test cells for receiving fluid to be diagnostically tested. Each of the test cells includes identification information including indicia which is indicative of a particular diagnostic test to be performed by the electronic instrument upon the fluid contained within the test cell. The indicia on a particular test cell are unique to that particular test cell so that no two test cells contain the same indicia. This feature is particularly important to the present invention as it precludes a test cell from ever being used twice. Each test cell is sized and shaped for engagement by the instrument. The instrument includes a reader for reading the indicia on the test cell prior to engagement of the test cell by the instrument. The diagnostic test to be performed is selected by the instrument based upon the identification information obtained from the indicia on the test cell.

The Lauks et al. patent discloses an instrument for performing a variety of electrochemical measurements on blood or other fluids drawn into a disposable device. The disposable device includes a series of notches (28, 30, 32 and 34) which are utilized by the instrument after the disposable device is inserted into the instrument to indicate the particular test to be performed on the blood or other fluid within the disposable collection device. Significantly, the Lauks et al. patent contains no reader other than the reader which is utilized to decode the notch pattern on the device after the device has been inserted into the instrument. Thus, the Lauks et al. patent does not disclose the concept of indicia on the test cell or device nor does it disclose or suggest that the instrument include a reader for reading the indicia on the test cell prior to engagement of the test cell by the instrument as called for in claim 1 as amended.

The Ozawa et al. patent discloses an analyzing system which, referring to Fig. 1, includes a sample container (4), a reagent container (5), a sensor (2) and a controller (8). A fluid passage (9) is provided to permit a pump (7) to draw fluid from both the sample container and the reagent container in such a manner that the fluid passes by the actual sensor (10) as shown in Fig. 2. The sensor (2) also includes a nonvolatile memory (11) and the entire sensor is adapted to be

removable from the controller to permit replacement of the sensor as needed. Significantly, there is no "test cell" as that term is understood in the present application. In addition, the Ozawa et al. system is adapted for multiple fluid analyses utilizing the same sensor.

In the background section of the Ozawa et al. patent at column 1 beginning at line 18 there is a discussion regarding the use of bar codes for the purpose of "representing the kind and lot number of a reagent included in the vessel". Although this is a clear recognition of the use of a bar code for lot numbers, since the Ozawa et al. patent does not include any type of test cell there is clearly no recognition of the desirability of putting a bar code on a test cell which is adapted to be inserted into diagnostic equipment. Further, there is nothing in this portion of Ozawa et al. patent which would teach or suggest the use of a unique bar code on a test cell in order to preclude the test cell from being reused.

Commencing at the bottom of column 5 and extending through the top portion of column 6 there is a discussion of the information which may be included in the nonvolatile memory of the sensor of Ozawa et al. Although this information is useful with respect to functional information concerning the sensor, there is nothing in this portion of the Ozawa et al. patent which would lead one skilled in the art to include unique identification information on a test cell for insertion into a medical diagnostic instrument to prevent the test cell from being used more than once.

Claim 1 has been amended in order to clarify, in significant detail, the uniqueness of the indicia of the test cell and to further clarify that the unique indicia is used by the instrument to prevent a diagnostic test from being performed on a test cell that has been previously used. It is respectfully submitted that these claimed features are not disclosed, taught or suggested in either the Lauks et al. patent or the Ozawa et al. patent. Accordingly, it is respectfully submitted that claim 1, as amended, as well as dependent claims 2-12, 17, 18, 21, 24, 26-28, 30 and 35-38 distinguish patentably over the combination of the Lauks et al. and Ozawa et al. patents.

Claims 13-16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lauks et al. and Ozawa et al. in view of U.S. Patent No. 4,797,188 (Tomita). Claims 25 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lauks et al. and Ozawa et al. in view of U.S. Patent No. 4,798,705 (Jakubowicz et al.). Claims 31-34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lauks et al. and Ozawa et al. in view of U.S. Patent No. 5,405,510 (Betts et al.). It is respectfully submitted that

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neither the Tomita, Jakubowicz et al. or Betts et al. references disclose, teach or suggest the above-discussed features of claim 1 as amended, which are not disclosed, taught or suggested by the Lauks et al. or Ozawa et al. patents. Accordingly, it is respectfully submitted that claims 13-16, 25, 29 and 31-34 distinguish patentably over the cited references at least because of their dependency from claim 1.

Beginning at paragraph 8 and extending through paragraph 11 of the last office action the Examiner raised several issues concerning the claim language, most of which were discussed the telephone interview. It is believed that all of the issues raised by the Examiner have been adequately addressed by amending claim 1 as set forth above.

In view of the foregoing amendment and discussion, as well as the comments during the telephone interview, it is respectfully submitted that the present application, including claim 1 as amended, as well as dependent claims 2-18, 21 and 24-38 is in condition for allowance and such action is respectfully solicited.

Respectfully submitted,

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(Date)

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